

# PATENT COOPERATION TREATY


## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 14 FEB 2006

Applicant's or agent's file reference LODM/P31853PC		<b>FOR FURTHER ACTION</b>		WIPO PCT See Form PCT/PEA/416
International application No. PCT/GB2004/004580		International filing date (day/month/year) 29.10.2004		Priority date (day/month/year) 30.10.2003
International Patent Classification (IPC) or national classification and IPC A23L1/015, A61K35/78, A23C9/00				
Applicant LODERS CROKLAAN BV				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 4 sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand  27.05.2005		Date of completion of this report  13.02.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Rinaldi, F  Telephone No. +49 89 2399-7360		



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/004580

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-20 as originally filed

**Claims, Numbers**

1-23 received on 16.08.2005 with letter of 15.08.2005

**Drawings, Sheets**

1/1 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing *(specify)*:
  - ☐ any table(s) related to sequence listing *(specify)*:
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing *(specify)*:
  - ☐ any table(s) related to sequence listing *(specify)*:

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 19-21

because:

☒ the said international application, or the said claims Nos. 19-21, as far as industrial applicability is concerned relate to the following subject matter which does not require an international preliminary examination (specify):

**see separate sheet**

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☒ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT  
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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-23
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-23
Industrial applicability (IA)	Yes: Claims	1-18,22-23
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The subject-matter of present claims 19-21 refers at least implicitly to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to novelty, inventive step and industrial applicability of the subject-matter of these claims (Art.34(4)(a)(I) PCT).

**Re Item V**

**Reasoned statement under Art.35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

- 1 Reference is made to the following documents:
  - D1: US-A-5 607 971 (AL-MAHMOUD MOHSEN ET AL) 4 March 1997 (1997-03-04)
  - D2: US-A-5 466 453 (UCHIDA YUKIO ET AL) 14 November 1995 (1995-11-14)
  - D3: US-A-5 690 984 (LIM JUNG GEUN) 25 November 1997 (1997-11-25)
  - D4: US-B1-6 329 000 (JI LING) 11 December 2001 (2001-12-11)
  - D5: DATABASE FSTA [Online] INTERNATIONAL FOOD INFORMATION SERVICE (IFIS), FRANKFURT/MAIN, DE; 2000, EUN-JU KIM ET AL: "Bread properties utilizing extracts of pine needle according to preparation method." XP002272259 Database accession no. 2000-00-m0004
  - D6: DATABASE FSTA [Online] INTERNATIONAL FOOD INFORMATION SERVICE (IFIS), FRANKFURT/MAIN, DE; 1999, YOUNG-AE OH ET AL: "Effect of addition of water extract of pine needle on tissue of kimchi." XP002272260 Database accession no. 1999-00-j0385
  - D7: WO 02/101025 A (KWON JAY YUNE ;KOREA BIOTECH CORP (KR); VLADIMIR BAKHAREV A (RU)) 19 December 2002 (2002-12-19)
  - D8: US-A-5,494,667
- 2 The subject-matter presently claimed is obvious in the sense of Art.33(3) PCT.
  - 2.1 Beneficial effects of pine needle extracts such as for instance lowering of blood pressure are known in the art, e.g. from D2 or D4 (for details on relevant passages,

please see ISR). These documents also disclose that pine needle extracts are used in food products including dairy products and also in dietetic products. Also, a large variety of substances is known to be present in pine needle extracts, for instance several organic acids such as shikimic acid, GABA and quinine acid to name but a few (see col.2 l.37-47 of D8).

- 2.2 D1 discloses that isocupressic acid is undesirable in as far as it is known in the art to induce early abortion in pregnant beef cattle (col.2 l.40-49). While it might be argued that the said disclosure only refers to compositions comprising particularly high concentrations of isocupressic acid, it cannot be denied that in the food field scientific arguments are not well received by the consumer. If the consumer believes that a substance is connected with a health risk, he will refuse the product altogether. Well founded reasoning as to why a risk is minimal or does not exist or is statistically not relevant will not reach the average consumer. It is considered that the average consumer, probably even a male consumer, would not accept a product that is somehow connected to the risk of abortion. Obviously, a substance with such a bad publicity or reputation is undesirable in a health product.
- 2.3 The closest prior art are documents D2 or D4 which disclose therapeutic effects of pine needle extracts and the use thereof in various food products (for details on relevant passages, please see ISR).
- 2.4 The technical problem is judged to be provision of a pine needle extract having beneficial effects and having a lowered risk on the user or at least providing a better acceptance with the consumer.
- 2.5 Apart from warning from the presence of isocupressic acid in pine needle extract, D1 also teaches that pine needle extract fractionation will lead to products of pine needle extract that are free from isocupressic acid and yet provide desired, beneficial health effects (col.5 l.43-col.10 l.38; col.15 l.55-64). D1 demonstrates that a variety of substances having therapeutic effects apart from isocupressic acid can be found in pine needle extract (see e.g. claims 7 and 11).
- 2.6 In view of what is stated above, it appears to be obvious for the one skilled in the art to provide pine needle extracts having reduced amounts of isocupressic acid, while maintaining all other beneficial substances present in the pine needle extract. In fact, the one skilled in the art would aim at selectively reducing the amount of isocupressic acid while maintaining all other beneficial components, including the above mentioned organic acids. The one skilled in the art would do this with a reasonable

expectation of success, because he knows that other substances and not isocupressic acid or at least not only isocupressic acid is responsible for the therapeutic effect.

- 3 In principle, the same arguments apply to D3 and D5-D7 which all disclose beneficial effects of pine needle extracts.

**Re Item VIII**

**Certain observations on the international application**

The subject-matter of present claims 3 and 4 appears to be redundant (Art.6 PCT).

Claims

1. Composition which is obtainable as an extract from pine needles, having therapeutic activity, comprising isocupressic acid compounds in an amount of less than 0.01 wt% and further comprising one or more organic acids.
2. Composition according to Claim 1, which contains isocupressic acid compounds in an amount of less than 0.005 wt%, preferably less than 0.003 wt%.
3. Composition according to Claim 1 or Claim 2 comprising at least two components A and B, wherein compound A is selected from the group consisting of phytosterol, polyphenols, bioflavonoids, tannins, organic acids and their complexes and compound B is selected from the group consisting of amino acids, peptides, proteins, quercetin, terpenoids, flavonol glycosides, biflavones, proanthocyanidins, polyprenols, lignans and minerals.
4. Composition as claimed in Claim 1 or Claim 2 which comprises a compound A selected from the group consisting of phytosterol, polyphenols, bioflavonoids, tannins, organic acids and their complexes and a compound B selected from the group consisting of amino acids, peptides, proteins, quercetin, terpenoids, flavonol glycosides, biflavones, proanthocyanidins, polyprenols, lignans and minerals.
5. Composition according to Claim 3 or Claim 4, wherein A is present in an amount of from 5 to 60 wt %, preferably 10 to 50 wt%, most preferably 15 to 40 wt%, and B is present in an amount of from 1 to 15 wt %, preferably 2 to 12wt %, most preferably 3 to 10 wt%, based on the weight of the composition.



6. Composition according to any one of the preceding claims which comprises shikimic acid in an amount of from 10 % to 50 % by weight of the composition.
7. Composition according to any one of the preceding claims which comprises quinic acid in an amount of from 5 % to 30 % by weight of the composition.
8. Foodstuff, food supplement or pharmaceutical composition comprising a composition of any one of Claims 1 to 7.
9. Dairy based food product comprising a composition as claimed in any one of Claims 1 to 7.
10. Dairy based food product according to Claim 9 having a water content of from 0.5 to 99.5 wt %, preferably 20 to 90 wt%, most preferably 30 to 85 wt%.
11. Dairy based food product according to Claim 9 or Claim 10 which is an oil in water (O/W) emulsion, a bicontinuous emulsion or a duplex W/O/W emulsion.
12. Dairy based food product according to Claim 9, which is a cream, milk, water continuous or bicontinuous spread, confectionery or sweet spread, chocolate, snack bar, nutritional bar, ice cream, confectionery filling or topping, bakery filling or topping, yoghurt, drinkable yoghurt, curd cheese, milk shake, slimming drink, cheese or cheese spread.
13. Dairy based food product according to any one of Claims 9 to 12, comprising a fat phase that displays a solid fat content (measured by NMR on a non-stabilised fat) at 5°C (=N5) of >10, preferably >20, and at 35°C (=N35) of <20, preferably <10, most preferably less than 5.

14. Dairy based food product as claimed in any one of Claims 9 to 13 which is essentially free of trans fatty acids.
15. Dairy based food product according to any one of Claims 9 to 14 which comprises from 0.05wt% to 10wt% of the composition of any one of Claims 1 to 7.
16. Dairy based food product according to any one of Claims 9 to 15 which has one or more of the following properties compared to a corresponding product that does not contain the composition: improved hardness, improved texture, improved aeration, improved spreadability, improved oral properties, improved mouthfeel, improved flavour, better colour, improved viscosity, improved whipping properties and improved ease of processing.
17. Composition as claimed in any one of Claims 1 to 7, foodstuff, food supplement or pharmaceutical composition as claimed in Claim 8 or dairy based food product as claimed in any one of Claims 9 to 15 for use to lower blood pressure in mammals, particularly in humans.
18. The use of a composition as claimed in any one of Claims 1 to 7, a foodstuff, food supplement or pharmaceutical composition as claimed in Claim 8 or a dairy based food product as claimed in any one of Claims 9 to 15 in the manufacture of an agent for lowering blood pressure in mammals, particularly in humans.
19. A method of lowering blood pressure in a mammal, particularly a human, which comprises providing the mammal with an effective amount of a composition as claimed in any one of Claims 1 to 7, a foodstuff, food supplement or pharmaceutical composition as claimed in Claim 8 or a dairy based food product as claimed in any one of Claims 9 to 15.
20. A method of improving one or more properties of a food product selected from hardness, texture, aeration, spreadability, oral properties, mouthfeel,

flavour, colour, viscosity, shape retention, ease of processing and health properties, which comprises incorporating into the food product a composition comprising one or more organic compounds, said composition being obtainable as an extract from pine needles, having therapeutic activity and comprising isocupressic acid compounds in an amount of less than 0.01 wt% and further comprising one or more organic acids.

21. Use of a material comprising one or more organic compounds, said material being obtainable as an extract from pine needles, having therapeutic activity and comprising isocupressic acid compounds in an amount of less than 0.01 wt% and further comprising one or more organic acids, for improving one or more properties of a food product selected from hardness, texture, aeration, spreadability, oral properties, mouthfeel, flavour, colour, viscosity, shape retention, ease of processing and health properties.

22. Process for producing the composition of any one of Claims 1 to 7, which comprises the following steps:

- a. treating pine needles with a solvent selected from water, organic solvents and mixtures thereof, to form a first extract;
- b. removing isocupressic acid compounds from the first extract, preferably by treatment with an ion exchange resin; and
- c. optionally, filtering and concentrating the treated extract to obtain the composition as a powder or a concentrate.

23. Process as claimed in Claim 22, wherein prior to step (a), the pine needles are pretreated with a non-polar solvent.